LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: Getz Pharma (Pvt) Ltd

1.0 General information

1.1 Name of Inspected company	Getz Pharma (Pvt) Ltd
1.2 Physical address	Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi 74900, Pakistan.
1.3 Corporate address	Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi 74900, Pakistan.
1.4 Summary of the main activities performed	Manufacture of Oral Solid dosage forms (Tablets, Capsules, Oral Powders for suspension and Sachets), Sterile (Liquid and Powder injectables), Biological Products, Metered Dose Inhalers, Dry Powder Inhalers and Metered Dose Inhalers
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the manufacture of general: • Oral Solid Dosage Forms – Tablets (Coated and uncoated)
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products which have been submitted for registration with the Medicines Control Authority of Zimbabwe (MCAZ)
1.7 Inspectors	Mr. Tendai Samkange – **Lead Inspector** Mr. Clive S. Kamhoti – **Co-inspector**
1.8 Date of Inspection	13th to 14th March, 2025

2.0 Abbreviations List

Abbreviation	Expanded Form
AHU	Air Handling Unit
API	Active Pharmaceutical Ingredient
EDI	Electrode Deionization
EM	Environmental Monitoring
HVAC	Heating, Ventilation, and Air Conditioning
ISO	International Organization for Standardization
LAF	Laminar Air Flow
MCAZ	Medicines Control Authority of Zimbabwe
NLT	Not Less Than
NVPC	Non-Viable Particle Count
OOS	Out of Specification
PIR	Public Inspection Report
PM	Preventive Maintenance
PQR	Product Quality Review
PV	Process Validation
QC	Quality Control
SOP	Standard Operating Procedure
TRS	Technical Report Series
WHO	World Health Organization

3.0 Summary

3.1 Brief summary about the facility

Get Pharma (Pvt) Ltd, Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi 74900, Pakistan, site under the scope of the inspection is used for the manufacture of Oral Solid dosage forms (Tablets, Capsules, Oral Powders for suspension and Sachets), Sterile (Liquid and Powder injectables), Biological Products, Metered Dose Inhalers, Dry Powder Inhalers and Metered Dose Inhalers.

The Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate audited the block manufacturing Oral Solid Dosage Forms. The audit was conducted from the 13th to 14th of March 2025. The company had been audited by other regulatory agencies listed in the table below.

Country	Agency
Ghana	FDA - Ghana
Iraq	MOH Iraq
Uzbekistan	MOH Uzbekistan
Belarus	MOH Belarus (EAEU Member State)

Libya	Ministry of Health, Pharmacy & Medical Devices Department
Malaysia	National Pharmaceutical Regulatory Agency
Syria	Syrian Arab Republic MOH
Phillipines	Republic of the Phillipines FDA
Geneva	World Health Organization
Ivory Coast	Ministere De La Sante Et De L Hygiene Publique
Tanzania	Tanzania Food and Drug Authority (TFDA)
Kenya	Pharmacy & Poisons Board (PPB)
Yemen	Supreme Board of Drug & Medical Appliances (SBDMA)
Geneva	World Health Organization
Nigeria	National Agency for Food & Drugs Administration & Control (NAFDAC)
Sudan	National Medicines & Poisons Board (NMPB)
Uganda	National Drug Authority
Kazakhstan	MOH Kazakhstan
DRC	ACCOREP

3.2 General Information about the Company and the Site

This was an initial inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support registration of products in Zimbabwe. The inspection was product-based and focused on the products that were intended for the Zimbabwean market, as provided below:

Product	**Dosage Form**	**Registration number**
Empaglifozin (Empiget) 25mg Tablet	Oral Solid Dosage Form - Tablet (Film Coated)	Pending Registration
Moxifloxacin Hydrochloride (Moxiget) 400mg Tablet	Oral Solid Dosage Form - Tablet (Film Coated)	Pending Registration

The inspection was conducted over two (2) days. The first day involved an introduction and company presentation meeting attended by senior members of the Getz Pharma team and the MCAZ inspectorate.

The inspection was conducted with reference to and in accordance with the WHO Good Manufacturing Practices detailed in the Technical Report Series 986, Annex 2 of 2014, among

other relevant current guidelines. The inspection was conducted in an open and cooperative atmosphere.

3.3 Areas inspected *(Not exhaustive)*

- **Quality Management**: Product Quality Review (PQR), Quality Risk Management, Deviation control, finished product and starting material batch release, Contract agreements and Supplier approval.
- **Materials Management**: Receipt, handling, quarantine, sampling, release, reject, temperature (and humidity) monitoring and dispensing.
- **Good Practices in Production**: Production areas, production equipment, documentation and instructions, sanitation cleaning and maintenance, batch records, calibration, contamination control, in process controls.
- **Quality Control**: Review of test procedures and specifications.
- **Utilities**: HVAC, Purified Water, Compressed Air system
- **Environmental Monitoring**: EM programme
- **Equipment qualification** and preventive maintenance

3.4 Utilities

a. Water Purification system
b. HVAC system
c. Compressed Air System

3.5 Documentation reviewed *(Not exhaustive)*

As stated in the final report

4.0 System Summaries

Walk-through Inspection

The walk-through inspection followed the logical flow of materials, that is from receiving raw materials to the final packaging and storage of the finished pharmaceutical products.

Warehouse

Materials were managed through an electronic system i.e SAP system. The SAP system had modules dedicated to Material Management, Production Planning, Quality as well as Sales & Distribution. The SAP system was audited and found to be tallying with paper-based records.

Production

The warehouse was inspected. There was adequate handling of starting materials. The dispensary and sampling areas were inspected, and these were found in state of good repair. The manufacturing (Granulation, compression and primary packaging) areas were inspected, and were generally satisafctory.

Batch Manufacturing Records
The batch manufacturing records of products in the scope of the inspection were reviewed and considered to be satisfactory. All the machine setup parameters were defined. Line clearance was being executed. IPQC tests were executed at set intervals as stipulated in the BMR.

Annual Product Quality Review
The annual product quality reviews (APQR) of products of interest were reviewed. The PQR included a review of all the product quality review elements stated in WHO TRS 986 Annex 2 guidelines.

Process Validation
The process validation protocols and reports of products in the scope of the inspection were reviewed. The acceptance criteria were well defined. Three batches were considered for validations triggered by major and critical changes.

Cleaning Validation
The documents describing the approached to cleaning validations were reviewed and considered to be satisfactory.

Preventative maintenance program
The site preventative maintenance program was reviewed. There was a generalized SOP for preventative maintenance and equipment-based SOPs for preventative maintenance. The frequency of PM for production equipment was based on several factors such as frequency of breakdowns, criticality of equipment *et cetera*.

Vendor approval
The SOP for vendor approval for Raw and packaging materials was reviewed. The roles and responsibilities of the Head QA was clearly outlined in the procedure and included overseeing vendor audits. There was provision for vendor rating and disqualification.

Quality Control

Analytical Worksheets
There was adequate control of the analytical worksheets at the facility.

Related substances
There was adequate monitoring of related substances in the finished formulations in the scope

of the inspection.

Equipment
Critical analytical equipment such as the dissolution apparatus, HPLCs, measuring balances were available in the laboratory. The SOP for calibration and utilization were provided. Approach to audit trail review was verified.

Area Qualifications/HVAC qualification
Qualification of cleanrooms was in line with ISO 14644 guidelines.

Purified Water System (PW)
The pretreatment, generation and distribution line were inspected. The approach to sanitization of the water system was verified. The approach to preventative maintenance was verified. Critical parameters were being monitored online with provision of failure safe mechanisms. Sanitization records and critical parameters trend reports were submitted for review.

Preventive maintenance
The SOP for preventative maintenance was submitted for review. There was provision of checklists for preventative maintenance. Examples of preventative maintenance checklists were submitted for review to ascertain application of the procedure.

5.0 Observations

As stated in the final report

6.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report, **Getz Pharma (Pvt) Ltd** located at, **Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi 74900, Pakistan**, was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of General Oral Solid Dosage Forms.

All the non-compliances observed during the inspection listed in the full report were addressed by the manufacturer to a satisfactory level prior to the publication of the MCAZ PIR.

The site will be reinspected **3 years** from the date of the last inspection in line with the risk-based reinspection frequency determination.

7.0 References

1. WHO good manufacturing practices for pharmaceutical products: main principles. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eight Report* Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html

2. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8, https://www.who.int/publications/m/item/Annex-8-trs-1010

3. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3 https://cdn.who.int/media/docs/default-source/medicines/norms-and standards/guidelines/production/trs1019-annex3-gmp-validation.pdf?sfvrsn=9440a5c_0&download=true

4. Supplementary guidelines on good manufacturing practices: validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report*. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4 http://www.who.int/medicines/publications/pharmprep/en/index.html

5. WHO good practices for pharmaceutical microbiology laboratories. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report*. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html

6. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. *WHO Expert Committee on specifications for pharmaceutical preparations*. *Forty-third report.* Geneva, World Health Organization, 2009. (WHO Technical Report Series, No. 953), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html

7. WHO guidelines on quality risk management. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report* Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2

http://www.who.int/medicines/publications/pharmprep/en/index.html

8. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty Ninth Report* Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3
http://www.who.int/medicines/publications/pharmprep/en/index.html

9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty Ninth Report* Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
http://www.who.int/medicines/publications/pharmprep/en/index.html